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510(k) Summary
for the L-Varlock Lumbar Cages

JUN 30 2008

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the L-Varlock Lumbar Cages

Date Prepared: February 20, 2008

1. **Submitter:**
Kiscomedica
Parc Technologique
2 Place Berthe Morisot
69800 ST PRIEST
FRANCE

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** L-Varlock Lumbar Cages
Common Name: intervertebral body fusion device
Classification Name: intervertebral body fusion device
Class II per CFR Section 888.3080
MAX

3. **Predicate or legally marketed devices which are substantially equivalent:**
The L-Varlock Lumbar Cage is substantially equivalent to similar previously cleared lumbar intervertebral body fusion devices.

4. **Description of the device:**
L-Varlock Lumbar Cage is implanted via a posterior approach and supplemented by posterior fixation. Two devices are used. Main features of the L-Varlock lumbar cage are:
   - Different heights for accurate enlargement of the foramina
   - Different widths and lengths to achieve excellent stability at the instrumented level while preserving the patient's anatomy.
   - Large graft space to achieve good bony fusion
   - Large cortical interface to ensure a good bony fusion.
   - Toothed outer walls prevent implant back out.
   - The rounded geometry of the anterior end of the cage avoids damage to the anterior vascular structures.

Materials:
L-Varlock lumbar Cages are manufactured from titanium alloy (Ti6Al4V-Eli, ASTM norm F136).

Function:
Lumbar interbody cages are one of the treatment options for low back pain.

5. **Intended Use:**
The L-Varlock Lumbar Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s).

L-Varlock Lumbar implants are to be used with autogenous bone graft and implanted via an open posterior approach. L-Varlock Lumbar implant is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

6. **Comparison of the technological characteristics of the device to predicate and legally marketed devices:**

   The L-Varlock Lumbar Cage is similar to the predicate devices in terms of indications for use, design, material, and function.

7. **Summary of Nonclincal Tests**

   Tests performed according to ASTM F2077/F2267 indicate that the L-Varlock Lumbar Cages meet the required mechanical acceptance criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kiscomedica
% The OrthoMedix Group, Inc.
Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, TX 78681

JUN 30 2008

Re: K080537
Trade/Device Name: L-Varlock Lumbar Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: May 27, 2008
Received: May 29, 2008

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

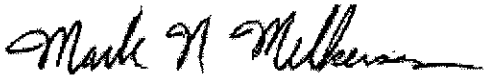
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K080537

Device Name: L-Varlock Lumbar Cage

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080537